

# HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

## UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under  
37 C.F.R. 1.53(b))

Attorney Docket No.

0975.1005-008

First Named Inventor or  
Application Identifier

Junming Le

Express Mail Label No.

EL551547474US

Title of  
Invention

ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS FACTOR

### APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO:

Assistant Commissioner for Patents  
Box Patent Application  
Washington, D.C. 20231

1. ☒ Fee Transmittal Form  
(Submit an original, and a duplicate for fee processing)

6. ☐ Microfiche Computer Program (Appendix)

2. ☒ Specification **Total Pages 164**

- (preferred arrangement set forth below)
- Descriptive title of the invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to microfiche Appendix
- Background of the Invention
- Summary of the Invention
- Brief Description of the Drawings
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

7. ☒ Nucleotide and/or Amino Acid Sequence Submission  
(if applicable, all necessary)

- a. ☒ Computer Readable Copy
- b. ☒ Paper Copy (identical to computer copy)

**6 Pages**

c. ☒ Statement verifying identity of above copies

3. ☒ Drawing(s) (35 U.S.C. 113) **Total Sheets 37**

- ☒ Formal ☐ Informal
- ☐ Fig. of the Drawings for Publication ☐

4. ☒ Oath or Declaration/POA **Total Pages 16**

- a. ☐ Newly executed (original or copy)
- b. ☒ Copy from a prior application (37 C.F.R. 1.63(d))  
(for continuation/divisional with Box 17 completed)  
**[NOTE Box 5 below]**
  - i. ☐ **DELETION OF INVENTOR(S)**  
Signed statement attached deleting  
inventor(s) named in the prior  
application, see 37 C.F.R. 1.63(d)(2)  
and 1.33(b).

5. ☒ Incorporation By Reference (useable if Box 4b is checked)  
The entire disclosure of the prior application, from which a  
copy of the oath or declaration is supplied under Box 4b, is  
considered as being part of the disclosure of the accompanying  
application and is hereby incorporated by reference therein.

### ACCOMPANYING APPLICATION PARTS

8. ☐ Assignment Papers (cover sheet & documents)  
☒ Assignee - Centocor, Inc., Malvern, Pennsylvania  
New York University, New York, New York

9. ☐ 37 C.F.R. 3.73(b) Statement ☐ Power of Attorney  
(when there is an assignee)

10. ☐ English Translation Document (if applicable)

11. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS  
Citations

12. ☐ Preliminary Amendment

13. ☒ Return Receipt Postcard (MPEP 503)  
(Should be specifically itemized)

14. ☐ Small Entity ☐ Statement filed in prior application,  
Statement(s) status still proper and desired

15. ☐ Certified Copy of Priority Document(s)  
(if foreign priority is claimed)

16. ☐ Nonpublication Request (check parent application)

17. ☒ Other: Remarks Letter

18. If a **CONTINUING APPLICATION**, check appropriate box and supply the requisite information:

☐ Continuation ☒ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 09/133,119

Prior application information: Examiner: K. Canella

Group Art Unit: 1642

### 19. CORRESPONDENCE ADDRESS

NAME	Carolyn S. Elmore				
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Signature

*Deirdre E. Sanders*

Date

*January 8, 2001*

Submitted by

Deirdre E. Sanders

Reg. Number

42,122

# HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

## FEE TRANSMITTAL FOR PATENT APPLICATIONS

Attorney Docket Number	0975.1005-008
Application Number	
First Named Inventor	Junming Le

01/08/01  
09/756301  
Jc950 U.S. PTO

CLAIM CALCULATION (includes any preliminary amendment)

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
TOTAL CLAIMS (37 CFR 1.16(c) or (j))	55	- 20* =	35	x \$ 18 =	\$ 630
INDEPENDENT CLAIMS (37 CFR 1.16(b) or (i))	14	- 3** =	11	x \$ 80 =	\$ 880
MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.16(d))				+ \$ 270 =	\$
				BASIC FEE (37 CFR 1.16(a) or (h))	\$ 710
				Total of above Calculations =	\$ 2220
				Reduction by 50% for filing by small entity (37 CFR 1.9, 1.27, 1.28) =	\$
				TOTAL =	\$ 2220
				Surcharge - Late Filing of Declaration or Filing Fees (37 C.F.R. 1.16(e)) =	\$
				Petition for Extension of Time Fee (37 C.F.R. 1.17) =	\$
				Assignment Recordation Fee = (only when filed with application)	\$
				TOTAL =	\$ 2220

\* Reissue claims in excess of 20 and over original patent  
\*\* Reissue independent claims over original patent

### 1. Small entity status:

- a. ☐ A small entity statement is enclosed.
- b. ☐ A small entity statement was filed in the prior non-provisional application and such status is still proper and desired.
- c. ☐ Is no longer claimed.

2. ☒ A general authorization is hereby granted to charge deposit account number 08-0380 for any fees required under 37 CFR 1.16 and 1.17 in order to maintain pendency of this application. A copy of this authorization is enclosed for accounting purposes.

3. ☒ A check is enclosed for \$2220.00. ☐ Please charge \$[ ] to Deposit Account No. 08-0380.

4. ☐ Other: \_\_\_\_\_

Signature	<i>Deirdre E. Sanders</i>	Date	<i>January 8, 2001</i>
Submitted by Typed or Printed Name	Deirdre E. Sanders	Reg. Number	42,122

**PTA - EXPRESS MAIL ONLY**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb,  
David M. Knight and Scott Siegel

Divisional Application of

Application No.: 09/133,119  
Filed: August 12, 1998

For: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN  
TUMOR NECROSIS FACTOR

<p>Date: <u>01-08-01</u></p> <p>EXPRESS MAIL LABEL NO. <u>EL551 547 474 US</u></p>
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REMARKS

Box PATENT APPLICATION  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The above-captioned application is a divisional of application number 09/133,119, filed on August 12, 1998 to which priority is claimed under 35 U.S.C. §120.

The Specification has been revised to incorporate amendments filed in the parent application and to correct minor typographical errors and informalities. The Related Applications paragraph has been revised and updated to include the parent application and issued patents. The discussion of WEHI cytotoxicity assays of fusion proteins has been moved from Example XXVI to Example XXVII for clarity.

Three incomplete sentences in the Specification have been completed for clarity. The first two sentences of the description of Figures 31A-31C have been amended to read: "Figures 31A-31C are graphical representations showing that fusion proteins protected WEHI 164 cells from TNF $\alpha$  cytotoxicity. Cells were first sensitized to TNF $\alpha$  with actinomycin D and then

incubated in 2 ng/ml TNF $\alpha$  with varying concentrations of TNF $\alpha$  overnight at 37°C.” See page 15, lines 12-15. The sentence in Example XXVI bridging page 145, line 29 - page 146, line 2, has been amended to read: “pH 730 contains coding sequences for all three constant domains of human IgG1 and was designed to accomodate the Xba1 fragments of pH7C707 at a unique Xba1 site upstream of the IgG1 coding sequences (Figure 28).” Support for these amendments is found in application 08/010,406 (the ‘406 application), filed January 29, 1993, which is entirely incorporated into the present Specification by reference (see page 1, lines 4-18 of the present Specification). Specifically, support for the amendment on page 15, lines 12-15 of the present Specification is found in the ‘406 application on page 8, lines 19-26, and the accompanying ‘406 Figures 5A-C. Support for the amendment on page 145, line 29 - page 146, line 2 of the present Specification is found on page 21, lines 31-34 of the ‘406 application.

The “Sequence Listing” (sheets 1/6 through 6/6) has been inserted.

Figures 16A-16B and Figures 32A-32B have been deleted and Figures 17A-31 and Figures 33A-36 have been renumbered accordingly. Formal drawings are being filed in lieu of the informal drawings originally filed with the parent application. Please note that this deletion and renumbering of the figures took place in the parent application (09/133,119), and it is being done in the instant application to be consistent. Formal Figure 32 has been revised to correct a typographical error in the figure legend.

Claims 1-34 have been omitted and new Claims 1-55 have been added.

If the Examiner desires, Applicants will produce a redlined version or other comparison document comparing this application with the immediate parent thereof. No new matter has been added. As such, a copy of the declaration from the parent application is being filed herewith.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Deirdre E. Sanders

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Dated: January 8, 2001

Date: <u>01-08-01</u>
EXPRESS MAIL LABEL NO. <u>EL551547 474 US</u>

jc950 U.S. PTO  
09/756301  
01/08/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight  
and Scott Siegel  
Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR  
NECROSIS FACTOR

TRANSMITTAL OF SEQUENCE LISTING IN COMPUTER READABLE FORM  
IN COMPLIANCE WITH 37 C.F.R. §§1.821(e) AND (f)

Box Sequence  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Transmitted herewith is a copy of the "Sequence Listing" in computer readable form as required by 37 C.F.R. §1.821(e). As required by 37 C.F.R. §1.821(f), Applicant's Attorney hereby states that the content of the "Sequence Listing" in paper form and of the computer readable form of the "Sequence Listing" are the same.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Date: January 8, 2001